Site visit inspection report on compliance with HTA licensing standards
Inspection date: **18-19 February 2020**

North Devon District Hospital

HTA licensing number 12401

Licensed under the Human Tissue Act 2004

Licensed activities

The table below shows the activities this establishment is licensed for and the activities currently undertaken at the establishment.

Area	Making of a post-mortem examination	Removal from the body of a deceased person (otherwise than in the course of an anatomical examination or post-mortem examination) of relevant material of which the body consists or which it contains, for use for a scheduled purpose other than transplantation	Storage of the body of a deceased person or relevant material which has come from a human body for use for a scheduled purpose
North Devon District Hospital	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology Department	-	-	*Carried out*
Accident and Emergency (A&E) Department	-	*Carried out*	-

Summary of inspection findings

The HTA found the Designated Individual (DI) and the Licence Holder (LH) to be suitable in accordance with the requirements of the legislation.

Although the HTA found that North Devon District Hospital (the establishment) had met the majority of the HTA's standards, five major and two minor shortfalls were found against standards for Governance and Quality, Traceability and Premises, Facilities and Equipment.

The HTA has assessed the establishment as suitable to be licensed for the activities specified, subject to corrective and preventative actions being implemented to meet the shortfalls identified during the inspection.

Compliance with HTA standards

Major shortfalls

Standard	Inspection findings	Level of shortfall
GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	The audit schedule does not include a sufficient number of vertical and horizontal audits of licensed activities. The establishment carried out only one audit relating to licensed activities in 2019. This audit was based on only the standards where advice and guidance was given at the last HTA inspection in 2015.	**Major (Cumulative)**
b) Audit findings document who is responsible for follow-up actions and the timeframe for completing these	Findings from the 2019 audit do not have defined deadlines for completion of follow-up actions and corrective actions have not been implemented within reasonable timeframes.	

T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail

c) Three identifiers are used to identify bodies and tissue, (for example post mortem number, name, date of birth/death), including at least one unique identifier	The establishment's procedures for identification of bodies do not always use a minimum of three identifiers of the deceased. • Identification of bodies for release from the mortuary to funeral directors may be performed using only two identifiers of the deceased provided by the funeral directors. • Identification for viewings of paediatric bodies may be based on only two identifiers of the deceased provided by the family at the time of arranging a viewing and upon arrival of the family prior to the viewing.	**Major**
PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue		
a) The premises are clean and well maintained	The mortuary facilities are showing signs of wear. • There is exposed wood on the rear doors at the entrance of the building and entrance to the viewing room. • There are areas of exposed plaster in the corridor to the body store and in the body store. • The floor in the body store and post mortem (PM) room is cracked and this has started to expose the floor underneath. • There are areas of rust along the skirting of the fridges. • The freezer seal is broken at the top of the freezer. The above issues may pose a health and safety risk to staff as these areas cannot be cleaned and disinfected adequately.	**Major**

PFE2 There are appropriate facilities for the storage of bodies and human tissue

e) Fridge and freezer units are alarmed and the alarms are tested regularly to ensure that they trigger when temperatures go out of upper or lower set range	There is no formal testing of the fridge and freezer temperature alarms to ensure call-out procedures work and are followed. There is only a locally audible temperature alarm for the fetal fridge. Out of hours, mortuary staff rely on porters who may enter the mortuary to contact them if they hear the alarm. The temporary body storage unit does not have a temperature alarm.	**Major**
PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
a) Items of equipment in the mortuary are in good condition and appropriate for use	There is a significant amount of rust on trolleys, tables and stools in the PM room. This means that these items of equipment cannot be cleaned and disinfected adequately.	**Major**

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings).	The establishment does not receive confirmation that PM specimens are received at the toxicology laboratory.	**Minor**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
f) Temperatures of fridges and freezers are monitored on a regular basis	The establishment does not have a formal system to review trends in storage temperatures. In addition, the establishment does not have a system to monitor temperatures of the fetal fridges or temporary body storage units out of hours.	**Minor**

The HTA requires the DI to submit a completed corrective and preventative action (CAPA) plan setting out how the shortfalls will be addressed, within 14 days of receipt of the final report (refer to Appendix 2 for recommended timeframes within which to complete actions). The HTA will then inform the establishment of the evidence required to demonstrate that the actions agreed in the plan have been completed.

Advice
The HTA advises the DI to consider the following to further improve practice:

Number	Standard	Advice
1.	C1(a)	The DI is advised to document the procedure to be followed in the rare event that staff seek consent for a paediatric PM examination.
2.	GQ5(a)	The DI is advised to update the standard operating procedure for managing HTA reportable incidents to reflect the most recent HTA guidance (published in May 2019).
3.	GQ6(a)	The DI is advised to risk assess mortuary staffing levels.
4.	T1(b)	Mortuary staff are advised to update the storage location recorded in the mortuary register when bodies are moved to freezer storage.

Background
North Devon District Hospital (the establishment) has been licensed by the HTA since February 2007. This was the third site visit inspection of the establishment; the most recent previous inspection took place in May 2015. Since the previous inspection, the establishment has introduced a new consent training programme.

Description of inspection activities undertaken
The HTA's regulatory requirements are set out in Appendix 1. The inspection team covered the following areas during the inspection:

Standards assessed against during inspection
All 72 HTA licensing standards were covered during the inspection (standards published 3 April 2017).

Review of governance documentation

The inspection team reviewed policies and procedural documents relating to licensed activities, cleaning records for the mortuary, contracts for servicing of equipment and records of servicing, audits, risk assessments, meeting minutes, temperature monitoring for the storage units, reported incidents, and staff training records.

Visual inspection

The inspection team carried out a visual inspection of the body storage areas, PM room, viewing room, contingency storage and the pathology department where PM tissue is stored. The A&E and maternity departments were not included in the visual inspection because the establishment reported no storage of relevant material takes place in these areas. The processes for removal of material in the A&E department were reviewed during the inspection.

Audits

The inspection team performed traceability audits of four bodies in storage. Identification details were crosschecked between the identification band on the body and the mortuary register. No discrepancies were found. The inspection team also audited release and receipt of a body in the mortuary (refer to shortfall against standard T1(c)).

Audits were conducted of tissue taken at PM examination for four PM cases. Information was crosschecked between the mortuary documentation, Coroner's paperwork, family wishes forms and the histology database. No discrepancies were found.

Meetings with establishment staff

The inspection team met with staff carrying out processes under the licence, including mortuary staff, porters who admit bodies into the mortuary, consent seekers for adult and perinatal PM examinations, a pathologist who conducts PM examinations and the DI.

Material held for the police

Under section 39 of the Human Tissue Act 2004 (HT Act), relevant material held for criminal justice purposes is outside the scope of HTA regulation and is not subject to the licensing requirements for storage. However, in response to a recommendation resulting from the 2012 report of the Association of Chief Police Officers' audit of tissue held under police authority, that police exhibits held on HTA licensed premises should be included within the regular HTA inspection process, police holdings stored in a designated area in histology were reviewed by the

HTA during the inspection. Any findings in relation to police holdings have been shared with the Home Office, but do not appear in this report as they are outside the scope of the HT Act.

Report sent to DI for factual accuracy: 9 March 2020

Report returned from DI: 11 March 2020

Final report issued: 20 March 2020

Completion of corrective and preventative actions (CAPA) plan

Based on information provided, the HTA is satisfied that the establishment has completed the agreed actions in the CAPA plan and in doing so has taken sufficient action to correct all shortfalls addressed in the Virtual Regulatory Assessment Report.

Date: 24 May 2021

Appendix 1: The HTA's regulatory requirements

Prior to the grant of a licence, the HTA must assure itself that the DI is a suitable person to supervise the activity authorised by the licence and that the premises are suitable for the activity.

The statutory duties of the DI are set down in Section 18 of the Human Tissue Act 2004. They are to secure that:

- the other persons to whom the licence applies are suitable persons to participate in the carrying-on of the licensed activity;
- suitable practices are used in the course of carrying on that activity; and
- the conditions of the licence are complied with.

Its programme of site visit inspections to assess compliance with HTA licensing standards is one of the assurance mechanisms used by the HTA.

The HTA developed its licensing standards with input from its stakeholders. They are designed to ensure the safe and ethical use of human tissue and the dignified and respectful treatment of the deceased. They are grouped under four headings:

- consent
- governance and quality systems
- traceability
- premises facilities and equipment.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that there has been a shortfall against a standard, the level of the shortfall is classified as 'Critical', 'Major' or 'Minor' (see Appendix 2: Classification of the level of shortfall). Where HTA standards are fully met, but the HTA has identified an area of practice that could be further improved, advice is provided.

HTA inspection reports are published on the HTA's website.

Appendix 2: Classification of the level of shortfall

Where the HTA determines that a licensing standard is not met, the improvements required will be stated and the level of the shortfall will be classified as ‘Critical’, ‘Major’ or ‘Minor’. Where the HTA is not presented with evidence that an establishment meets the requirements of an expected standard, it works on the premise that a lack of evidence indicates a shortfall.

The action an establishment will be required to make following the identification of a shortfall is based on the HTA's assessment of risk of harm and/or a breach of the Human Tissue Act 2004 (HT Act) or associated Directions.

1. **Critical shortfall:**

   A shortfall which poses a significant risk to human safety and/or dignity or is a breach of the HT Act or associated Directions

   or

   A combination of several major shortfalls, none of which is critical on its own, but which together could constitute a critical shortfall and should be explained and reported as such.

   A critical shortfall may result in one or more of the following:

   - A notice of proposal being issued to revoke the licence
   - Some or all of the licensable activity at the establishment ceasing with immediate effect until a corrective action plan is developed, agreed by the HTA and implemented.
   - A notice of suspension of licensable activities
   - Additional conditions being proposed
   - Directions being issued requiring specific action to be taken straightaway

2. **Major shortfall:**

   A non-critical shortfall that:

   - poses a risk to human safety and/or dignity, or
   - indicates a failure to carry out satisfactory procedures, or
   - indicates a breach of the relevant Codes of Practice, the HT Act and other relevant professional and statutory guidelines, or

- has the potential to become a critical shortfall unless addressed

or

A combination of several minor shortfalls, none of which is major on its own, but which, together, could constitute a major shortfall and should be explained and reported as such.

In response to a major shortfall, an establishment is expected to implement corrective and preventative actions within 1-2 months of the issue of the final inspection report. Major shortfalls pose a higher level of risk and therefore a shorter deadline is given, compared to minor shortfalls, to ensure the level of risk is reduced in an appropriate timeframe.

3. **Minor shortfall:**

   A shortfall which cannot be classified as either critical or major, but which indicates a departure from expected standards.

   This category of shortfall requires the development of a corrective action plan, the results of which will usually be assessed by the HTA either by desk based review or at the time of the next site visit.

   In response to a minor shortfall, an establishment is expected to implement corrective and preventative actions within 3-4 months of the issue of the final inspection report.

Follow up actions

A template corrective and preventative action plan will be sent as a separate Word document with both the draft and final inspection report. Establishments must complete this template and return it to the HTA within 14 days of the issue of the final report.

Based on the level of the shortfall, the HTA will consider the most suitable type of follow-up of the completion of the corrective and preventative action plan. This may include a combination of

- a follow-up site visit inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next routine site visit inspection.

After an assessment of the proposed action plan establishments will be notified of the follow-up approach the HTA will take.